

CMS ISSUES COVID-19 VACCINATION REQUIREMENTS FOR MEDICARE- AND MEDICAID-CERTIFIED PROVIDERS AND SUPPLIERS

Hodgson Russ Healthcare and Labor & Employment Alert
November 5, 2021

On November 4, 2021, the Centers for Medicare & Medicaid Services (CMS) issued an Interim Final Rule with Comment Period, and a list of frequently asked questions (FAQs), setting out the COVID-19 vaccination requirements that most Medicare- and Medicaid-certified providers and suppliers will need to meet to participate in the Medicare and Medicaid programs. The Interim Final Rule is available [here](#), and the FAQs are available [here](#).

Also on November 4, 2021 the Occupational Safety and Health Administration (OSHA) issued a separate Emergency Temporary Standard (ETS) establishing minimum vaccination, vaccination verification, face covering, and testing requirements applicable to employers with at least 100 employees. You can read about the OSHA ETS requirements in our companion alert [here](#).

Which healthcare providers and suppliers are covered under the Interim Final Rule?

The Interim Final Rule applies to Medicare- and Medicaid-certified providers and suppliers, ranging from hospitals to hospices and rural health clinics to skilled nursing facilities (nursing homes), for which CMS establishes health and safety standards (Conditions of Participation, Conditions for Coverage, or Requirements for Participation). These include the following (with the relevant section of Title 42 of the Code of Federal Regulations in parentheses):

- Ambulatory Surgical Centers (ASCs) (§ 416.51);
- Hospices (§ 418.60);
- Psychiatric residential treatment facilities (PRTFs) (§ 441.151);
- Programs of All-Inclusive Care for the Elderly (PACE) (§ 460.74);
- Hospitals (acute care hospitals, psychiatric hospitals, hospital swing beds, long term care hospitals, children's hospitals, transplant centers, cancer hospitals, and rehabilitation hospitals/inpatient rehabilitation facilities) (§ 482.42);

Attorneys

Christine Bonaguide
Luisa Bostick
Joseph Braccio
David Bradley
Jane Bello Burke
Roopa Chakkappan
Glen Doherty
Andrew Drilling
Reetuparna Dutta
Ryan Everhart
Joshua Feinstein
Andrew Freedman
Peter Godfrey
John Godwin
Charles H. Kaplan
Karl Kristoff
Christopher Massaroni
Elizabeth McPhail
Lindsay Menasco
Michelle Merola
Kinsey O'Brien
Matthew Scherer
Gary Schober
David Stark
Jeffrey Swiatek
Michael Zahler

Practices & Industries

Healthcare

CMS ISSUES COVID-19 VACCINATION REQUIREMENTS FOR MEDICARE- AND MEDICAID-CERTIFIED PROVIDERS AND SUPPLIERS

- Long Term Care (LTC) Facilities, including Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs), generally referred to as nursing homes (§ 483.80);
- Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) (§ 483.430);
- Home Health Agencies (HHAs) (§ 484.70);
- Comprehensive Outpatient Rehabilitation Facilities (CORFs) (§§ 485.58 and 485.70);
- Critical Access Hospitals (CAHs) (§ 485.640);
- Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services (§ 485.725);
- Community Mental Health Centers (CMHCs) (§ 485.904);
- Home Infusion Therapy (HIT) suppliers (§ 486.525);
- Rural Health Clinics (RHCs)/Federally Qualified Health Centers (FQHCs) (§ 491.8); and
- End-Stage Renal Disease (ESRD) Facilities (§ 494.30).

Labor & Employment

Which healthcare providers and suppliers are not covered under the Interim Final Rule?

The Interim Final Rule applies only to Medicare- and Medicaid-certified facilities. It does not apply directly to physician offices, adult care facilities, or other persons and entities that CMS does not directly regulate.

Other COVID-19 vaccination requirements, such as the OSHA requirements applicable to certain employers, may apply to entities that Interim Final Rule does not cover.

Additionally, in New York, the mandatory vaccination requirements in the emergency regulation at 10 NYCRR § 2.61 apply to “covered entities.” These include:

- any facility or institution included in the definition of “hospital” in section 2801 of the Public Health Law, including but not limited to general hospitals, nursing homes, and diagnostic and treatment centers;

CMS ISSUES COVID-19 VACCINATION REQUIREMENTS FOR MEDICARE- AND MEDICAID-CERTIFIED PROVIDERS AND SUPPLIERS

- any agency established pursuant to Article 36 of the Public Health Law, including but not limited to certified home health agencies, long term home health care programs, acquired immune deficiency syndrome (AIDS) home care programs, licensed home care service agencies, and limited licensed home care service agencies;
- hospices as defined in section 4002 of the Public Health Law; and
- adult care facilities under the regulatory authority of the New York State Department of Health, as set forth in Article 7 of the Social Services Law.

What are the implementation due dates?

The Interim Final Rule requires health care providers to establish a process or policy to fulfill the staff vaccination requirements over two phases.

- For Phase 1, within 30 days after publication in the Federal Register, or by December 5, 2021, staff at all health care facilities included within the Interim Final Rule must have received, at a minimum, the first dose of a primary series or a single dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its patients.
- For Phase 2, within 60 days after publication in the Federal Register, or by January 4, 2022, staff at all health care provider and supplier types included in the Interim Final Rule must complete the primary vaccination series (except for those who have been granted exemptions from the COVID-19 vaccine or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by CDC).

Which staff are subject to the CMS COVID-19 vaccination requirement?

Each facility's COVID-19 vaccination policies and procedures must apply to the following facility staff, regardless of clinical responsibility or patient contact and including all current staff as well as any new staff, who provide any care, treatment, or other services for the facility and/or its patients: facility employees; licensed practitioners; students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or other arrangement.

Which staff are not subject to the CMS COVID-19 vaccination requirement?

The vaccination requirements do not apply to individuals who provide services 100% remotely, such as fully remote telehealth or payroll services.

How will the provider or supplier determine, document and monitor vaccination status?

Under the Interim Final Rule, acceptable forms of proof of vaccination include the following:

- CDC COVID-19 vaccination record card (or a legible photo of the card);
- Documentation of vaccination from a health care provider or electronic health record;

CMS ISSUES COVID-19 VACCINATION REQUIREMENTS FOR MEDICARE- AND MEDICAID-CERTIFIED PROVIDERS AND SUPPLIERS

- State immunization information system record; or
- If vaccinated outside of the U.S., a reasonable equivalent of any of the previous examples.

The provider or supplier must appropriately document all staff COVID-19 vaccines. Examples of appropriate places for vaccine documentation include: a facility immunization record; health information files; or other relevant documents. The provider or supplier must keep all medical records, including vaccine documentation, confidential and store it separately from an employer's personnel files, in accordance with the federal Americans with Disabilities Act (ADA) and the Rehabilitation Act. While providers and suppliers have flexibility to use the appropriate tracking tools of their choice, CDC offers an optional staff vaccination tracking tool that is available [here](#).

Does the Interim Final Rule include testing requirements for unvaccinated staff?

No, the Interim Final Rule requires staff vaccination only, but facilities may voluntarily institute testing alongside other infection prevention measures such as physical distancing and source control.

Separately, in September 2020, CMS published an interim final rule with comment period (available [here](#)) establishing new requirements for nursing homes to test facility residents and staff for COVID-19. CMS expects continued compliance with this requirement.

Additionally, CMS encourages facilities not covered by this regulation to review the OSHA Emergency Temporary Standard, which we discussed in a prior alert available [here](#), for separate vaccination and testing requirements.

What does "fully vaccinated" mean?

Consistent with CDC guidance, CMS will consider staff to be fully vaccinated if it has been two or more weeks since the completion of a primary vaccination series for COVID-19. The completion of a primary vaccination series means having received a single-dose vaccine or all doses of a multi-dose vaccine.

The Food and Drug Administration ("FDA") has approved, and CDC has recommended, boosters for certain groups that previously completed a primary vaccination series. For the purposes of the Interim Final Rule, however, staff who have completed a COVID-19 primary vaccination series authorized or licensed by the FDA, or listed by the World Health Organization (WHO) for emergency use, do not need to document receipt of additional or booster doses.

Staff who have who have completed the primary series for the vaccine received by the Phase 2 implementation date are considered to have met these requirements, even if they have not yet completed the 14-day waiting period required for full vaccination.

Are exemptions allowed?

Yes. CMS recognizes that certain allergies, recognized medical conditions, or religious beliefs, observances, or practices, may provide grounds for exemption. Further, CMS recognizes that there are federal laws, including the ADA, section 504 of the Rehabilitation Act, section 1557 of the Affordable Care Act, and Title VII of the Civil Rights Act of 1964, that prohibit discrimination based on race, color, national origin, religion, disability and/or sex, including pregnancy. CMS recognizes

CMS ISSUES COVID-19 VACCINATION REQUIREMENTS FOR MEDICARE- AND MEDICAID-CERTIFIED PROVIDERS AND SUPPLIERS

that, in some circumstances, employers may be required by law to offer accommodations for some individual staff members.

CMS requires facilities to allow for exemptions to staff with recognized medical conditions for which vaccines are contraindicated (as a reasonable accommodation under the ADA) or religious beliefs, observances, or practices (established under Title VII of the Civil Rights Act). While recognizing that employers have the flexibility to establish their own processes and procedures, including forms, CMS refers to The Safer Federal Workforce Task Force’s “request for a religious exception to the COVID-19 vaccination requirement” template, available [here](#), as an example.

CMS states that it intends the Interim Final Rule to preempt, consistent with the Supremacy Clause, inconsistent state and local laws as applied to Medicare- and Medicaid-certified providers and suppliers. This includes any state or local law to the extent it provides exemptions that are broader than those under federal law and inconsistent with the Interim Final Rule.

Does the Interim Final Rule require providers to develop written policies?

Yes. Providers must develop policies and procedures with processes to require vaccinations; determine exemption requests; mitigate transmission and spread for unvaccinated staff; track and document COVID-19 vaccination, booster and exemption status; and implement contingency plans. Providers and suppliers should refer to the specific regulatory provisions governing their respective operations for specific requirements.

New York healthcare providers that developed policies and procedures to comply with the New York emergency regulation should review those policies and procedures for compliance with the federal regulation.

If you have questions regarding CMS’s mandatory vaccination requirement, the New York mandatory vaccination requirement for healthcare workers, or how these developments may affect your healthcare operations, please contact [Jane Bello Burke](#) (518.433.2404), [Peter C. Godfrey](#) (716.848.1246), [Charles H. Kaplan](#), (646.218.7513), [Roopa R. Chakkappan](#) (716.848.1258), or any member of Hodgson Russ’s [Healthcare](#) or [Labor & Employment](#) Practices.